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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/396,985 09/15/99 BEUTLER B UTSD:602

HM22/0313

EXAMINER

ARNOLD WHITE & DURKEE  
P O BOX 4433  
HOUSTON TX 77057

EINSMANN, J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/369,985	ZIMMERBEUTEL ET AL.	
	Examiner Juliet C. Einsmann	Art Unit 1655	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> <b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>15 September 1999</u> . 2a) <input type="checkbox"/> This action is FINAL.                    2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-51</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input checked="" type="checkbox"/> Claims <u>1-51</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner. 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. § 119</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of the CERTIFIED copies of the priority documents have been: 1. <input type="checkbox"/> received. 2. <input type="checkbox"/> received in Application No. (Series Code / Serial Number) _____. 3. <input type="checkbox"/> received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).			
<b>Attachment(s)</b>			
14) <input type="checkbox"/> Notice of References Cited (PTO-892) 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .		17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 19) <input type="checkbox"/> Other: _____	

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, drawn to methods for screening for susceptibility for infection, classified in class 435, subclass 6.
  - II. Claims 23-27, 32-35, 41-44, 47-49, drawn to methods for reducing susceptibility of an animal to infection by providing a TLR-4 polypeptide, classified in class 514, subclass 2.
  - III. Claims 23-25, 28-31, 33-37, 41-42, 45-46, 48-51, drawn to methods for reducing susceptibility of an animal to infection by providing or inducing a nucleic acid, classified in class 514, subclass 44.
  - IV. Claims 38-40, drawn to methods for screening for modulators, classified in class 533, subclass 50.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in the instant case, the methods of these four groups are unrelated because they have different goals, require different reagents, and have different method steps.

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With respect to groups II and III, these groups are differentiated because while both groups have the goal of reducing the susceptibility of animals to infection, one group II does so by administering a polypeptide while group III accomplishes this goal using methods for administering polynucleotides. Claims 23-25, 33-35, 41-42, and 48-49 are drawn broadly so as to embrace both of these methods, and as such they have been included in both groups.

Claims 24 and 26 and all those that depend from them were treated as if they depend from claim 23 instead of claim 24 as was discussed by the examiner and Mark Wilson on March 7, 2000.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. A telephone call was made to Mark Wilson on March 7, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*JCF*  
JEFFREY FREDMAN  
PRIMARY EXAMINER

*Juliet C. Einsmann*

Juliet C. Einsmann  
Examiner  
Art Unit 1655

March 8, 2000